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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,016	STAHMANN ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *5,7-13,15-19,46-49,51,63,64,73 and 75-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,14,20-45,50,52-62,65-72,74 and 81-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/05, 7/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 5, 7-13, 15-19, 46-49, 51, 63, 64, 73, and 75-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 May 2007.

2. Applicant's election with traverse of claims 1-4, 6, 14, 20-45, 50, 52-62, 65-72, 74, and 81-104 in the reply filed on 11 May 2007 is acknowledged. The traversal is on the ground(s) that the designated species are not distinct, and that there is no burden on the examiner. This is not found persuasive because Applicant's arguments and examples of species overlap differ from the examiner's delineation of which claims are generic and which belong to various species. Specifically, Applicant uses "patient history" as a criteria overlapping several species as a reason they cannot be different species. Examiner designated claims directed to patient history as generic (for example, claim 80), and Applicant omitted such claims from their listing of what they believe to be generic. The arguments are therefore spurious. Applicant also has indicated that examination of all claims would not be impose a serious burden – Examiner disagrees, since examination of 104 claims directed to 13 different species would impose a very serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-4, 6, 14, 20-45, 50, 52-62, 65-72, 74, and 81-104 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-40 and 80-100 of copending Application No. 10/643154 (US Patent Application Publication 2005/0043772). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 6, 14, 25, 35, 38-45, 49, 68, 69, 71, 72, 74, 81, 82, 90, 95, 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazar (US Patent Application Publication 2004/0133079).

Regarding claims 1-4, 6, 14, 25, 35, and 38 Mazar discloses a method for predicting disordered breathing comprising detecting a physiological (respiratory quality) condition associated with disordered breathing, comparing the condition to one or more sets of disordered breathing prediction criteria, predicting the disordered breathing based on the comparison, and collecting data on the predictions and conditions, where the comparing and predicting are performed at least implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 33 and 34, since Mazar discloses prediction of a disordered breathing episode, Mazar discloses that "disordered breathing will occur during a particular time interval" and in "real-time".

Regarding claims 39 and 40, Mazar further discloses collecting data on the predictions, transmitting it to a separate device, and displaying it (paragraphs [0043]-[0044]).

Regarding claims 41-45, 49, and 53 Mazar discloses a method for predicting disordered breathing comprising detecting physiological or respiratory condition predisposing a patient to disordered breathing, comparing the one or more predisposing conditions to one or more sets of prediction criteria associated with disordered breathing, and predicting the disordered breathing in real time based on the

comparison, wherein the comparing and predicting are performed implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claim 52, Mazar discloses the detected condition comprising a first type of disordered breathing, and the prediction being that of a second type of disordered breathing (paragraph [0008]).

Regarding claims 56-60 and 66, Mazar discloses an automated method for predicting disordered breathing comprising detecting a precursor respiratory condition associated with an impending onset of disordered breathing, comparing the condition to a set of prediction criteria associated with disordered breathing, and predicting the disordered breathing based on the comparison, where the comparing and predicting are performed at least in part implantably (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 68, 69, 72, and 74, Mazar discloses a device comprising a detector system configured to detect conditions associated with disordered breathing and comprising an implantable sensor; and a prediction engine coupled to the detector system and configured to compare the detected conditions to one or more sets of prediction criteria and predict the disordered breathing based on the comparison, wherein the prediction engine includes an implantable component (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claims 71, 81, 82, 90, and 95-97, Mazar further discloses a patient input device, a network-accessible component, and a wirelessly connected component (paragraph [0044]), as well as a data storage unit (element 701; paragraph [0043]) and a display unit (paragraphs [0082]-[0083], [0088]).

Regarding claim 98, Mazar discloses a system comprising means for detecting one or more conditions associated with a patient's disordered breathing, means for comparing the one or more conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing, wherein at least one of the means for comparing and the means for predicting include an implantable component (paragraphs [0016], 0033]-[0035], [0038]).

Regarding claim 101, Mazar discloses an automated system comprising means for detecting one or more conditions predisposing a patient to disordered breathing, means for comparing the one or more predisposing conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing based on the comparison, wherein at least one of the means for comparing and the means for predicting includes an implantable component (paragraphs [0016], [0033]-[0035], [0038]).

Regarding claim 102, Mazar discloses a system for predicting disordered breathing comprising means for detecting one or more precursor conditions associated with disordered breathing, means for comparing the precursor conditions to one or more sets of disordered breathing prediction criteria, and means for predicting the disordered breathing based on the comparison, wherein at least one of the means for predicting and/or comparing includes an implantable component (paragraphs [0016], [0031]-[0035], [0038]).

Regarding claims 103 and 104, Mazar further discloses detecting both a respiratory condition and an additional physiological condition (paragraph [0016]).

7. Claims 1-4, 6, 14, 20-22, 26, 28, 35, 38, 41-45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner (US Patent 6415183).

Regarding claims 1-4, 6, 14, 35, and 38 Scheiner discloses a method for predicting disordered breathing comprising detecting a physiological (respiratory quality) condition associated with disordered breathing, comparing the condition to one or more sets of disordered breathing prediction criteria, predicting the disordered breathing based on the comparison, and collecting data on the predictions and conditions, where the comparing and predicting are performed at least implantably (column 5, lines 31-39 and 44-62; column 6, lines 8-13, 53-54, and 57-65).

Regarding claims 20 and 21, Scheiner further discloses the prediction criteria comprising a threshold and comparing the sensed criteria to the threshold (column 7, lines 21-27; column 8, lines 8-32).

Regarding claim 22, Scheiner further discloses comparing a relationship between two prediction criteria to a relationship criterion that corresponds to an onset of disordered breathing (figure 5).

Regarding claims 26 and 28, Scheiner further discloses establishing and adjusting a particular set of prediction criteria based on the conditions (column 8, lines 19-32).

Regarding claims 41-45, and 49 Scheiner discloses a method for predicting disordered breathing comprising detecting physiological or respiratory condition predisposing a patient to disordered breathing, comparing the one or more predisposing

conditions to one or more sets of prediction criteria associated with disordered breathing, and predicting the disordered breathing based on the comparison, wherein the comparing and predicting are performed implantably (column 5, lines 31-39 and 44-62; column 6, lines 8-13, 53-54, and 57-65).

8. Claims 1, 23, 24, 26-30, 68, 70, 83, 84, 87, and 98-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazar'161 (US Patent Application Publication 2004/0128161).

Regarding claim 1, Mazar'161 discloses a method for predicting disordered breathing comprising detecting a condition associated with disordered breathing, comparing the condition to a set of disordered breathing prediction criteria, and predicting the disordered breathing based on the comparison, where at least one of the predicting and comparing is performed implantably (paragraphs [0027]-[0031], [0061], [0066]-[0067]).

Regarding claims 23 and 24, Mazar'161 further discloses comparing the condition to the criteria by computing an estimated probability that disordered breathing will occur based on the condition by computing a composite estimated probability score, and comparing the estimated probability to a threshold probability associated with an onset of disordered breathing (paragraphs [0076]-[0079]).

Regarding claims 26-30, Mazar'161 further discloses implantably establishing and adjusting a particular set of prediction criteria based on the condition (paragraphs

[0076]-[0078]). Though Mazar'161 does not explicitly disclose deleting a set of criteria, the evolution of criteria naturally results in discarding previous sets of criteria.

Regarding claims 68, 70, and 87, Mazar'161 discloses an automated device comprising a detector system having a patient-external sensor configured to detect conditions associated with disordered breathing and a prediction engine coupled to the detector system and configured to compare the detected conditions to one or more sets of prediction criteria and predict the disordered breathing in real time based on the comparison, where the prediction engine includes an implantable component (paragraphs [0027]-[0031], [0034], [0061], [0066]-[0067]).

Regarding claims 83, 84, Mazar further discloses that the prediction engine is configured to establish the prediction criteria based on the detected conditions, and that it may adjust the set of criteria based on the detected conditions (paragraphs [0076]-[0078]).

Regarding claims 98-100, Mazar discloses a system comprising means for detecting one or more conditions associated with a patient's disordered breathing, means for comparing the condition(s) to one or more sets of disordered breathing prediction criteria, means for predicting the disordered breathing, wherein at least one of the means for comparing and/or predicting include an implantable component, and means for establishing and adjusting a particular set of prediction criteria (paragraphs [0027]-[0031], [0034], [0061], [0066]-[0067], [0076]-[0078]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazar in view of Nappholz (US Patent 4702253).

Mazar discloses all the elements of the claimed invention, as described above, except for monitoring a respiratory tidal volume pattern; Mazar's method of monitoring a patient's respiration is performed using thoracic impedance. Nappholz teaches a method of monitoring a patient's tidal volumes using thoracic impedance (column 2, lines 26-53), in order to accurately monitor the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Mazar and used the thoracic impedance measurements to monitor the patient's tidal volumes, as taught by Nappholz, in order to accurately monitor the patient.

11. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazar in view of Park (US 6741885).

Mazar discloses all the elements of the claimed inventions, as described above, except for the monitored condition being tidal volume patterns, such as hyperventilation; Mazar also discloses that the monitoring may be performed via thoracic impedance (paragraph [0038]). Park teaches a patient monitoring method comprising using thoracic impedance to monitor a patient's respiratory characteristics, such as tidal volume and hyperventilation (column 8, line 63 to column 9 line 7; column 14 line 61 to column 15 line 12), in order to accurately monitor the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Mazar and monitored the patient's tidal volume or hyperventilation, as taught by Park, in order to accurately monitor the patient's condition.

Allowable Subject Matter

12. Claims 31, 32, 36, 37, 50, 54, 55, 65, 67, 85, 86, 88, 89, and 91-94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the inventions of claims 31 and 85, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the prediction criteria may be adjusted

based on the detected condition by calculating an estimated accuracy for the particular set of prediction criteria, and adjusting the set based on the estimated accuracy.

The prior art of record fails to anticipate or make obvious the inventions of claims 32 and 86, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the prediction criteria may be adjusted based on the detected condition by calculating an estimated sensitivity for the particular set of prediction criteria, and adjusting the set based on the estimated sensitivity.

The prior art of record fails to anticipate or make obvious the inventions of claims 36 and 91-93, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, and also collecting data associated with the predictions comprising counting the disordered breathing predictions.

The prior art of record fails to anticipate or make obvious the inventions of claims 37 and 94, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, and also collecting data associated with the accuracy of predictions.

The prior art of record fails to anticipate or make obvious the method of claim 50, including, *inter-alia*, predicting disordered breathing by detecting a patient's snoring, comparing the snoring to a set of prediction criteria associated with disordered breathing, and predicting the occurrence of disordered breathing, where the comparing and/or predicting are done at least in part implantably.

The prior art of record fails to anticipate or make obvious the inventions of claims 54 and 88, including, *inter-alia*, predicting disordered breathing by detecting a condition

and comparing the condition to criteria, where the predicted occurrence will take place within 8 hours of the prediction.

The prior art of record fails to anticipate or make obvious the inventions of claims 55 and 89, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the predicted occurrence will take place the next time the patient is asleep.

The prior art of record fails to anticipate or make obvious the method of claim 65, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the condition is the detection of the periodicity of occurrences of the disordered breathing.

The prior art of record fails to anticipate or make obvious the method of claim 67, including, *inter-alia*, predicting disordered breathing by detecting a condition and comparing the condition to criteria, where the predicted occurrence will take place within 5 minutes of the prediction.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4365636 to Barker, which discloses similar a similar invention.

US Patent Application Publications 2004/0122488 and 2004/0116981 to Mazar, which disclose similar inventions.

US Patent 6580944 to Katz, which discloses a similar invention.

US Patent 6964641 to Cho, which discloses a similar invention.

US Patent 7225013 to Geva, which discloses a similar invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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